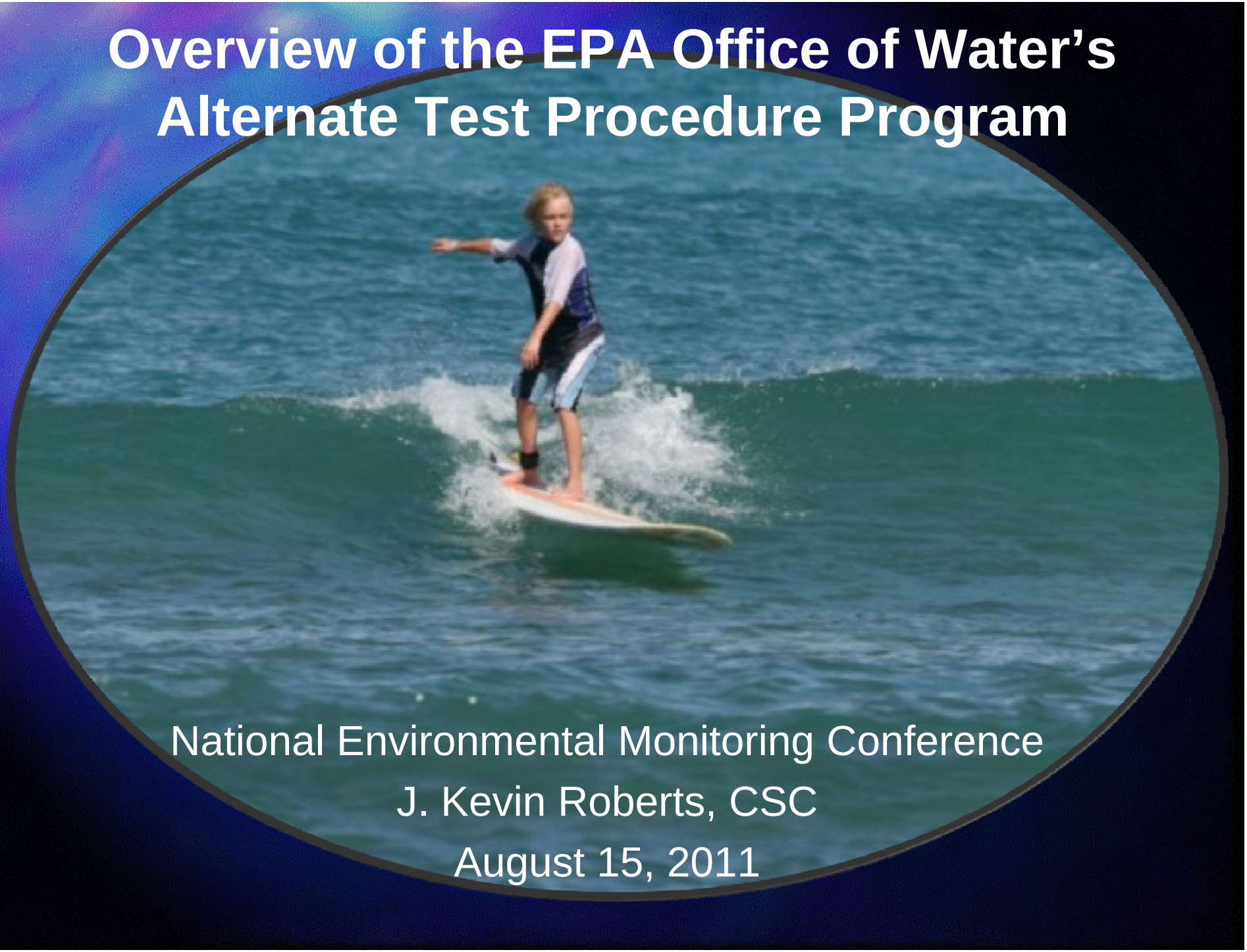
Overview of the EPA Office of Water's Alternate Test Procedure Program



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Background

The Office of Water maintains a program for organizations outside of EPA to apply for approval of methods other than those prescribed by the EPA in 40 CFR 136 or 141.

An ***ATP (alternate test procedure)*** uses the same determinative technique as that used in an EPA-approved method.

A ***new method*** uses a determinative technique that is different from that used in an EPA-approved method.

EPA OW's ATP Program

EPA OW's ATP Program is organized by analytical categories:

- Chemical methods
- Microbiological methods
- Whole Effluent Toxicity (WET) methods
- Radiochemical Methods

The following slides focus on the process for gaining approval of ATPs and new methods that measure inorganic and organic chemical parameters for nationwide use in compliance monitoring under the Clean Water Act.

ATP Program Management

The Clean Water Act (40 CFR 136) ATP program is managed by the Engineering and Analytical Support Branch (EASB).

Lemuel Walker manages the CWA ATP Program (walker.lemuel@epa.gov)
EASB has final authority regarding wastewater ATPs.

The Office of Groundwater and Drinking Water (OGWDW) provides concurrent review of drinking water ATPs (40 CFR 141).

Steve Wendelken manages the Drinking Water ATP Program (wendelken.steve@epa.gov)
OGWDW has final authority regarding drinking water ATPs.

CSC provides support to both aspects of OW's ATP program.

ATP and New Method Protocols

Separate protocols are available for ATPs and new methods:

Protocol for EPA Approval of Alternate Test Procedures for Organic and Inorganic Analytes in Wastewater and Drinking Water, EPA-821-B-98-002 (Revised March 1999)

Protocol for EPA Approval of New Methods for Organic and Inorganic Analytes in Wastewater and Drinking Water, EPA-821-B-98-003 (Revised March 1999)

These protocols may be viewed or downloaded on EPA's website at:

http://water.epa.gov/scitech/methods/cwa/atp/questions.cfm#askEPA

Performance Criteria Validation

OW's current chemical ATP and new method protocols include tiered validation and documentation requirements.

The tiered requirements were developed to reduce the validation burden for those seeking method approval without sacrificing data quality, by providing for validation against reference method performance criteria in most cases.

Performance criteria validation applies only to methods that measure distinct analytes or method modifications that will not result in changes to the forms and species of the analyte measured.

Method-Defined Parameters

Applications for approval of ATPs or new methods that measure method defined parameters are dealt with on a case-by-case basis and validation requirements may vary.

In all cases, a validation study plan must be submitted for review and comment and agreed upon prior to validation.

In general, validation of methods that measure “method-defined” parameters must be supplemented with side-by-side comparison of the results obtained from analysis of samples with the ATP or new method and those obtained from analysis of identical samples using an approved method.

Examples of chemical method-defined analytes include oil & grease, turbidity, TOC, BOD, and total cyanide.

Application Requirements

General application requirements for CWA ATPs are specified at 40 CFR Part 136.4, 136.5, and in the ATP and New method protocols

An initial application package should consist of:

- A completed ATP application form
- An explanation of why this modification falls outside the scope of 136.6
- A justification for the ATP or new method
- A method write-up for the ATP or new method
- A two-column side-by-side comparison which highlights the differences between the ATP or new method and an approved reference method
- Any existing supporting data and documentation

EPA will use this information to determine what additional data (if any) will be needed.

Flexibility at 40 CFR Part 136.6

The regulations at 40 CFR part 136.6 allow modifications to the approved test procedures provided that the underlying chemistry or the determinative technique is not changed.

In the past, letters were issued on a case-by-case basis stating that methods which incorporated these types of modifications were acceptable versions of the approved method and that they may be used for compliance monitoring.

Since publication of the March 12, 2007 Final Rule (72 FR 11200), letters are no longer being issued for these types of modifications.

ATP applications submitted for methods that include these types of modifications are returned to the applicant.

Examples

Modifications that fall under the flexibility at 40 CFR part 136.6

- The use of prepackaged reagents
- Changes between manual, flow analysis and discreet analyzer
- Changes in calibration range

Modifications that require approval as an ATP or new method

- Changes to the underlying chemistry of an approved method
- Changes to the determinative technique of an approved method
- Changes to methods that measure method defined analytes

Validation Studies

Chemical ATP performance is validated by comparing the results of validation studies against specified performance criteria

New method validation requires the method developer to generate performance criteria using data obtained from validation studies

The performance criteria of the new method will be evaluated against the criteria of approved methods

EPA **strongly** recommends that a validation study plan is submitted and agreed upon prior to beginning any method validation studies

Validation Requirements

	Number of		Number of Analysis Required			
Method Application	**Labs**	**Matrix Types**	**IPR – Reagent Water**	**IPR – Sample Matrix**	**MS/MSD**	**MDL**
Tier 3 – Multi-lab	9	9	36	0	18	63

Explanation of Validation Table

Reagent water IPR analyses

For validation of an ATP, the IPR tests demonstrate that the QC acceptance criteria for initial precision and recovery (IPR) and ongoing precision and recovery (OPR) of the designated EPA-approved method have been met.

For validation of a new method, the IPR tests are used to establish QC acceptance criteria for initial precision and recovery (IPR) and ongoing precision and recovery (OPR).

Required number of IPR analyses is four times the number of laboratories required to validate an ATP or new method, because each laboratory performs a 4-replicate IPR test

Explanation of Validation Table (cont.)

Matrix spike/matrix spike duplicate (MS/MSD) analyses

For validation of an ATP, the MS/MSD tests demonstrate that the MS/MSD recovery and precision of the EPA-designated approved method have been met.

For validation of a new method, the MS/MSD tests establish QC acceptance criteria for MS/MSD recovery and precision.

The required number of MS/MSD tests is two times the number of matrix types tested.

Explanation of Validation Table (cont.)

Method Detection Limit (MDL) analyses

A method detection limit (MDL) test must be performed in each laboratory using the ATP or new method.

40 CFR Part 136, Appendix B requires a minimum of seven tests per laboratory to determine an MDL

The number of MDL tests is seven times the number of laboratories required to validate an ATP or new method because each laboratory performs a 7-replicate IPR test

Validation Study Results

For both ATPs and new methods, the validation study report and supporting data must be provided to EPA as part of the final application.

- For ATPs, EPA reviews validation study results to verify that the ATP results meet the QC specifications of the designated EPA-approved method.

- For new methods, EPA uses the validation study report to determine the method's scientific merit, consistency, and appropriateness for compliance monitoring under CWA.

Approval Through Rulemaking

Rulemaking consists of :

A proposal to approve the method in the *Federal Register*, which includes:

- A *preamble* which summarizes the proposal
- A *docket*, which includes a copy of the method, validation data, and all supporting materials
- A 60-day public comment period (at least)

A response to comments and revision of the method, if appropriate

A final rule to promulgate the method in the *Federal Register* and to incorporate the method into the *Code of Federal Regulations*

The rulemaking process can take one year or more

Successful ATPs and New Methods

Proposed Method Update Rule published September 23, 2011

- Hach Company's Method 10360 Luminescence Measurement of Dissolved Oxygen (LDOR) in Water
- In-Situ Incorporated's Method 1002–8–2009 Dissolved Oxygen (DO) Measurement by Optical Probe
- In-Situ Incorporated's Method 1003–8–2009 Biochemical Oxygen Demand (BOD) Measurement by Optical Probe,
- In-Situ Incorporated's Method 1004–8–2009 Carbonaceous Biochemical Oxygen Demand (CBOD) Measurement by Optical Probe August 2009,
- Mitchell Method M5271 for measuring turbidity in wastewater
- Mitchell Method M5331 for measuring turbidity in wastewater
- Thermo Scientific's Orion Method AQ4500 for measuring turbidity in wastewater
- Systea Scientific, LLC's Systea Easy (1-Reagent) Nitrate Method.